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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/532,605	08/18/2005	Takehiro Miwa	Q87625	9927

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EXAMINER	
ARIANI, KADE	

ART UNIT	PAPER NUMBER
1651	

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12/02/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/532,605	MIWA ET AL.	
	Examiner	Art Unit	
	KADE ARIANI	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 August 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *6,9-11 and 17-42* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *6, 9-11,and 17-42* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *10/30/2008*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The amendment filed on August 18, 2008, has been received and entered.

Claims 1-5, 7, 8, and 12-16 have been canceled. New claims 21-42 have been added.

Claims 6, 9-11, and 17-42 are pending in this application and were examined on their merits.

IDS

The information disclosure statement (IDS) submitted on 10/30/2008 was filed after the mailing date of the Non-final rejection on 03/17/2008. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claim 7 has been cancelled, therefore, he rejection of Claim 7 under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex*

parte Dunki, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd.* v. *Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966), is withdrawn.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-5 have been cancelled therefore, the rejection of claims 1-5 under 35 U.S.C. 102 (b), as being anticipated by Olsen et al. (WO98/30682-A1), is withdrawn.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The rejection of Claims 1-20 under 35 U.S.C. 103(a) as being unpatentable over Shih et al. (US2002/0172989 A1) and in view of Olsen et al. (WO 98/30682-A1), is withdrawn due to Applicant amendments to the claims filed on 08/18/2008.

Claims 6, and 17-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shih et al. (US2002/0172989 A1) and in view of Olsen et al. (WO 98/30682-A1), and further in view of Genov et al. (Biochem J, 1982, Vol. 207, p.193-200).

Claims 6, and 17-30 are drawn to a method for digesting a protein highly resistant to denaturation and degradation, comprising the step of bringing the protein highly resistant to denaturation and degradation into contact with an enzyme exhibiting an activity of digesting a protein highly resistant to denaturation and degradation and having the following properties, hydrolyzing a peptide bond, MW 31,000, pI 9.3, optimum pH 9.0 to 10.0, optimum temperature for activity 60 to 70°C, exhibiting an activity of 2U/g or more as the activity of digesting a protein highly resistant to denaturation and degradation (determined as an activity of digesting keratin azure), derived from a microorganism belonging to genus *Bacillus*, wherein the enzyme is selected from the group consisting of an enzyme comprising the amino acid sequence of SEQ ID No:2, wherein the protein highly resistant to denaturation and degradation is a pathogenic prion protein, wherein the contacting step is carried out without preheating the subject, and wherein the contacting step is carried out without preheating the subject at 90°C or more.

Claims 9-11, and 31-42 are drawn to a method for detoxifying a pathologic prion protein, comprising the step of bringing a subject which may be contaminated with a pathological prion protein into contact with an enzyme exhibiting an activity of digesting a protein highly resistant to denaturation and degradation and having the following properties, hydrolyzing a peptide bond, MW 31,000, pI 9.3, optimum pH 9.0 to 10.0, optimum temperature for activity 60 to 70ºC, exhibiting an activity of 2U/g or more as the activity of digesting a protein highly resistant to denaturation and degradation (determined as an activity of digesting keratin azure), derived from a microorganism belonging to genus *Bacillus*, wherein the enzyme is selected from the group consisting of an enzyme comprising the amino acid sequence of SEQ ID No:2, wherein the protein highly resistant to denaturation and degradation is a pathogenic prion protein, wherein the contacting step is carried out without preheating the subject, and wherein the contacting step is carried out without preheating the subject at 90ºC or more.

Shih teaches a method for digesting of infectious prion proteins comprising the step of bringing the protein into contact with an enzyme, the enzyme is derived from *Bacillus licheniformis* (Abstract, Page 1 0002, 0006,0010, and Page 3 0054), wherein the contacting step is carried out without preheating the subject at 90ºC or more (page 2 0031). Shih teaches it will be recognized that any of a wide variety of proteases may be employed in the practice of the invention and that the choice of specific proteolytic enzyme will affect the choice of temperature that is used to carry the proteolytic degradation, as well as the choice of any elevate temperature treatment of the tissue before its exposure to the proteolytic enzyme (Page 3, 0046). Shih further teach

proteolytic enzymes include keratinase enzymes, subtilisins, and active fragments of a keratinase enzyme (Page 3 0053-0054). Shih teaches the method achieves a substantial advance in the art, permitting nutritional use of a material that would otherwise, in the absence of the treatment, constitute a biological hazard, and to avoid costs and infrastructure requirements for incineration and disposal of infected or contaminated animal tissue (page 4 0071). Shih further teaches a method for reduction of infective prion protein (a method for detoxifying a pathologic prion protein) (page 6 Claim 1). Shih teaches the enzyme is a serine protease (p.5 0086).

Shih does not teach the enzyme exhibiting, MW 31,000, pI 9.3, optimum pH 9.0 to 10.0, optimum temperature for activity 60 to 70°C, exhibiting an activity of 2U/g or more as the activity of digesting a protein highly resistant to denaturation and degradation (determined as an activity of digesting keratin azure), an enzyme comprising the amino acid sequences of SEQ ID NO: 2. However, Olsen et al. teach subtilisin DY, MW, of 27, 000 an enzyme comprising the amino acid sequences of SEQ ID NO: 2, (p.19, line 10).

Therefore, in view of the above teachings it would have been obvious to a person of ordinary skill in the art at the time the invention was made to substitute the enzyme in the method as taught by Shih with the enzyme as taught by Olsen et al. to provide a method for digesting a protein highly resistant to denaturation and degradation and a method for detoxifying a pathologic prion protein with predictable results of digesting a protein highly resistant to denaturation and degradation and detoxifying a pathologic prion protein. Because substitution of one known enzyme with another would have

yielded predictable results to one of ordinary skill in the art at the time the invention was made.

Response to Arguments

Applicant's arguments filed on 08/18/2008 have been fully considered but they are not persuasive.

Applicant argues that Olsen dose not teach the claimed agent, and while the presently claimed enzyme and subtilisin DY may share amino acid sequence, but they do not posses an identical chemical structure.

However, Applicant conflicts themselves. Because, specification page 33 2nd paragraph, disclose" it was confirmed that the amino acid sequence of the purified enzyme obtained in Example 1 is completely identical to the subtilisin DY".

Moreover, specification page 29 3rd paragraph, disclose " molecular weight of the enzyme capable of digesting a pathogenic prion protein was approximately 26,000"m, which is very close to the molecular weight taught by Olsen.

Moreover, Genov et al. teach subtilisin DY (derived from a Bacillus), is an alkaline serine protease and displays optimum pH about 10 for the proteolytic activity (see Genov et al. Introduction 1st column last paragraph and 2nd column 1st paragraph).

As mentioned immediately above, the claim methods would have been obvious because substitution of one known enzyme with another would have yielded predictable results to one of ordinary skill in the art at the time the invention was made.

Conclusion

No claims are allowed.

THIS ACTION IS MADE FINAL. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kade Ariani whose telephone number is (571) 272-6083. The examiner can normally be reached on 9:00 am to 5:30 pm EST Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on (571) 272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Kade Ariani
Examiner
Art Unit 1651

/Leon B Lankford/
Primary Examiner, Art Unit 1651